

Medical Policy and Coding Updates August 5, 2021

Special notices

Effective November 5, 2021

Allograft Injection for Degenerative Disc Disease, 7.01.166

New policy

Injecting a tissue graft from a donor into the space between the spinal vertebrae as a treatment of degenerative joint disease is considered investigational

Medical Necessity Criteria for Pharmacy Edits, 5.01.605

Testosterone Replacement Products

New drug added to policy

Aveed® (testosterone undecanoate)

Miscellaneous Oncology Drugs, 5.01.540

New drugs added to policy

- Abraxane® (paclitaxel protein-bound particles)
 - Treatment of metastatic breast cancer
 - Treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC)
 - Treatment of metastatic adenocarcinoma of the pancreas
- Arranon® (nelarabine)
 - Treatment of T-cell acute lymphoblastic lymphoma (T-ALL)
 - Treatment of T-cell lymphoblastic lymphoma (T-LBL)
- Empliciti® (elotuzumab)
 - Treatment of multiple myeloma
- Erwinaze® (asparaginase erwinia chrysanthemi)
 - As a part of a multi-agent chemotherapy regimen for the treatment of acute lymphoblastic leukemia (ALL)
- Halaven® (eribulin mesylate)
 - Treatment of metastatic breast cancer
 - Treatment of inoperable or metastatic liposarcoma
- Yondelis® (trabectedin)
 - Treatment of inoperable or metastatic liposarcoma or leiomyosarcoma



Non-covered Experimental/Investigational Services, 10.01.533

New policy

- The safety and/or effectiveness of treatments, procedures, equipment, drugs, drug usage, medical devices, or supplies that have not been supported by a review of published medical and scientific literature are considered experimental/investigational
- o This policy lists several services that are considered experimental/investigational

Effective October 1, 2021

Nerve Repair for Peripheral Nerve Injuries Using Synthetic Conduits or Allografts, 7.01.584 New policy

Synthetic conduits and nerve allografts are considered investigational for the repair or closure of nerve gaps from peripheral nerve injuries

Effective September 12, 2021

Updates to AIM Specialty Health® Clinical Appropriateness Guidelines

Effective for dates of service on and after September 12, 2021, the following updates will apply to the AIM Specialty Health® Clinical Appropriateness Guidelines for Advanced Imaging

Updates by section

Advanced Imaging of the Spine

Congenital vertebral defects

Added new requirement for additional evaluation with radiographs

Scoliosis

- Defined presurgical planning criteria
- Added requirement for radiographs and new or progressive symptoms for postsurgical imaging

Spinal dysraphism

Tethered cord

- o Revised diagnostic imaging strategy to limit CT use when MRI cannot be performed
- Added new requirement for ultrasound prior to advanced imaging for tethered cord in infants age 5 months or less



Multiple sclerosis

Added new criteria for imaging in initial diagnosis of MS

Spinal infection

 Aligned new diagnosis and management criteria with Infectious Disease Society of America (IDSA) and University of Michigan guidelines

Axial spondyloarthropathy

- Added definition of inflammatory back pain
- o Added diagnostic testing radiography requirements

Cervical injury

 Aligned pediatric cervical trauma criteria with American College of Radiology (ACR) guidelines

Thoracic or lumbar injury

- Revised diagnostic imaging strategy to include radiography and limited use of MRI for a known fracture
- Removed indication for follow-up imaging of progressively worsening pain without fracture or neurologic deficits

Syringomyelia

Removed surveillance imaging indication

Non-specific low back pain

 Aligned pediatric low back pain criteria with American College of Radiology (ACR) guidelines

Effective for dates of service on and after September 12, 2021, the following updates will apply to the AIM Specialty Health® Clinical Appropriateness Guidelines for Extremity Imaging

Updates by section

Advanced Imaging of the Extremities

Osteomyelitis or septic arthritis

Myositis

Removed CT as a follow-up to nondiagnostic MRI due to lower diagnostic accuracy of CT

Epicondylitis and Tenosynovitis - long head of biceps

Removed these sections due to lack of evidence supporting imaging for this diagnosis



Plantar fasciitis and fibromatosis

- Removed CT as a follow-up to nondiagnostic MRI due to lower diagnostic accuracy of CT
- Added specific conservative management requirements

Brachial plexus mass

Added specific requirement for suspicious findings on clinical exam or prior imaging

Morton's neuroma

o Added requirements for focused steroid injection, orthoses, and plan for surgery

Adhesive capsulitis

 Added requirement for planned intervention (manipulation under anesthesia or lysis of adhesions)

Rotator cuff tear

Labral tear - shoulder

Labral tear - hip

- o Defined specific exam findings and updated duration of conservative management
- o Updated recurrent labral tear to meet same criteria as an initial tear (shoulder only)

Triangular fibrocartilage complex tear

o Added requirement for radiographs and conservative management for chronic tear

Ligament tear - knee; meniscal tear

- o Added requirement for radiographs for specific scenarios
- Increased duration of conservative management for chronic meniscal tears

Ligament and tendon injuries - foot and ankle

Defined required duration of conservative management

Chronic anterior knee pain including chondromalacia patella and patellofemoral pain syndrome

 Increased duration of conservative management and specified requirement for chronic anterior knee pain

Intra-articular loose body

Added requirement for mechanical symptoms

Osteochondral lesion (including osteochondritis dissecans, transient dislocation of patella)

Added new requirement for radiographs

Entrapment neuropathy

Excluded carpal and cubital tunnel syndromes



Persistent lower extremity pain

- Defined duration of conservative management
- Excluded hip joint (addressed in other indications)

Upper extremity pain

- Excludes shoulder joint (addressed in other indications)
- Revised diagnostic testing strategy to limit CT use when MRI cannot be performed or is nondiagnostic

Knee arthroplasty, presurgical planning

Limited to MAKO and robotic assist arthroplasty cases

Perioperative imaging, not otherwise specified

Require radiographs or ultrasound prior to advanced imaging

Effective for dates of service on and after September 12, 2021, the following updates will apply to the AIM Specialty Health® Clinical Appropriateness Guidelines for Vascular Imaging

Updates by section

Vascular Imaging

Added alternative non-vascular imaging approaches, where applicable

Hemorrhage, Intracranial

- Specified clinical scenario for subarachnoid hemorrhage
- Added pediatric intracerebral hemorrhage indication

Horner's syndrome; Pulsatile tinnitus; Trigeminal neuralgia

Removed condition management indication for continued vascular evaluation

Stroke/TIA

Stenosis or occlusion (intracranial/extracranial)

- o Added acute and subacute time frames
- Removed carotid/cardiac workup requirement for intracranial vascular evaluation
- o Added condition management specifications
- Separated sections into anterior/posterior circulation (carotid artery and vertebral or basilar arteries, respectively)

Pulmonary Embolism

Added non-diagnostic chest radiograph requirement for all indications



o Added pregnancy-adjusted YEARS algorithm

Peripheral Arterial Disease

 Added new post-revascularization indication to both upper and lower extremity PAD evaluation

Effective September 3, 2021

Alpha1-Proteinase Inhibitors, 5.01.624

New policy

The following brand drugs have been added and may be considered medically necessary when criteria are met:

- Aralast® NP (alpha1-proteinase inhibitor (PI) [human])
- Glassia® (alpha1-PI [human])
- Prolastin®-C (alpha1-PI [human])
- Zemaira® (alpha1-PI [human])
 - Treatment of adults with emphysema due to hereditary deficiency of alpha1-PI (alpha1-antitrypsin deficiency)

Drugs for Rare Diseases, 5.01.576

New drugs added to policy

- Aldurazyme® (laronidase)
 - Treatment of mucopolysaccharidosis type I (MPS I), including Hurler, Hurler-Scheie, and Scheie forms, in patients age 6 months and older
- Brineura® (cerliponase alfa)
 - Treatment of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) in patients age 3 and older
- Gamifant™ (emapalumab-lzsg)
 - Treatment of adult and pediatric patients with primary hemophagocytic lymphohistiocytosis (HLH)
- Kanuma® (sebelipase alfa)
 - Treatment of lysosomal acid lipase (LAL) deficiency
- Naglazyme® (galsulfase)
 - Treatment of mucopolysaccharidosis type VI (MPS VI, also known as Maroteaux-Lamy syndrome), in patients age 3 months and older
- Sylvant® (siltuximab)
 - Treatment of patients with multicentric Castleman's disease (MCD) in patients age
 18 and older



Gonadotropin Releasing Hormone (GnRH) Analogs, 5.01.625

New policy

The following drugs have been added and may be considered medically necessary when criteria are met:

Breast cancer

- Zoladex® (goserelin)
 - Palliative treatment of advanced breast cancer in pre- and perimenopausal women

Central precocious puberty

- Fensolvi® (leuprolide acetate)
- Generic leuprolide
- Lupron Depot PED® (leuprolide acetate)
- Supprelin LA® (histrelin implant)
- Triptodur® (triptorelin),
- Vantas® (histrelin implant)
 - Treatment of children with abnormally early puberty

Endometriosis

- Generic leuprolide
- Lupaneta Pack® (leuprolide/norethindrone)
- Lupron Depot® (leuprolide acetate)
- Zoladex® (goserelin)
 - Management of endometriosis, including pain relief and reduction of endometriotic lesions
- Orilissa® (elagolix)
 - Treatment of moderate to severe pain associated with endometriosis

Gender dysphoria

- Fensolvi® (leuprolide acetate)
- Generic leuprolide
- Lupron Depot® (leuprolide acetate)
- Lupron Depot PED® (leuprolide acetate)
- Supprelin LA® (histrelin implant)
- Trelstar® (triptorelin pamoate)
- Triptodur® (triptorelin)
- Vantas® (histrelin implant)
 - Treatment of gender dysphoria in adolescents

Prostate cancer

- Eligard® (leuprolide acetate)
- Firmagon® (degarelix)



- Generic leuprolide
- Lupron Depot® (leuprolide acetate)
- Orgovyx® (relugolix)
- Trelstar® (triptorelin pamoate)
- Zoladex® (goserelin)
 - Palliative treatment of metastatic prostate cancer
- Zoladex® (goserelin)
 - Treatment of locally confined Stage T2b-T4 (Stage B2-C) prostate cancer when used in combination with flutamide

Uterine fibroids

- Generic leuprolide
- Lupron Depot® (leuprolide acetate)
 - Treatment of anemia due to uterine fibroids
 - To reduce the size of uterine fibroids prior to surgery
- Oriahnn® (elagolix/estradiol/norethindrone acetate)
 - Management of heavy bleeding related to uterine fibroids in premenopausal patients age 18 and older
- Zoladex® (goserelin)
 - Use as an endometrial-thinning agent prior to endometrial ablation for abnormal uterine bleeding

Effective August 6, 2021

Pharmacologic Treatment of Duchenne Muscular Dystrophy, 5.01.570

Site of service review added

Vyondys 53® (golodirsen)

Pharmacotherapy of Cushing's Disease and Acromegaly, 5.01.548

New drugs added to policy

- Bynfezia® Pen (octreotide)
- o Generic octreotide
- Sandostatin® (octreotide)
- Sandostatin® LAR Depot (octreotide)
- Somatuline® Depot (lanreotide)
 - Treatment of acromegaly in adults age 18 and over
 - Treatment of adults with inoperable, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs)
 - Treatment of adults with carcinoid syndrome



 Treatment of adults with profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas)

Site of Service: Infusion Drugs and Biologic Agents, 11.01.523

Site of service review added Vyondys 53® (golodirsen)

Medical policies

New medical policies Effective August 1, 2021

Prescription Digital Therapeutics, 13.01.500

New policy

- Therapeutic, evidence-based interventions delivered by software to treat, manage, and prevent behavioral and physical health diseases and disorders may be considered medically necessary when criteria are met
- o Certain FDA-approved prescription digital therapeutics are considered investigational

Pharmacy policies

New pharmacy policies

Chimeric Antigen Receptor Therapy for Multiple Myeloma, 8.01.66

New policy

The following drug has been added and may be considered medically necessary when criteria are met:

- Abecma® (idecabtagene vicleucel)
 - Treatment of relapsed or refractory multiple myeloma in patients age 18 and older

Revised pharmacy policies Effective August 1, 2021

Chimeric Antigen Receptor Therapy for Leukemia and Lymphoma, 8.01.63 Policy renamed



 From "Chimeric Antigen Receptor Therapy for Hematologic Malignancies" to "Chimeric Antigen Receptor Therapy for Leukemia and Lymphoma"

New drug added to policy

- o Breyanzi® (lisocabtagene maraleucel)
 - Treatment of relapsed or refractory, aggressive types of non-Hodgkin lymphoma

Policy statement added

o Documentation requirements for Breyanzi® (lisocabtagene maraleucel)

Epidermal Growth Factor Receptor (EGFR) Inhibitors, 5.01.603

New drug added to policy

- o Rybrevant™ (amivantamab-vmjw)
 - Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC)

Medical Necessity Criteria for Pharmacy Edits, 5.01.605

Brand Drugs for ADHD and Stimulants for Other Psychiatric Conditions

New drug added to policy

- Azstarys[™] (serdexmethylphenidate and dexmethylphenidate)
 - Treatment of attention deficit hyperactivity disorder (ADHD)

Antifungals

New drug added to policy

- Brexafemme® (ibrexafungerp)
 - Treatment of vulvovaginal candidiasis (VVC)

Chronic Kidney Disease Treatment

New policy section

New drug added to policy

- Farxiga® (dapagliflozin)
 - Treatment of chronic kidney disease

Continuous Glucose Monitoring (CGM) Supplies

New policy section

Quantity limits added

- Dexcom G6® Sensor
- Dexcom G6® Transmitter
- o Freestyle® Libre Sensor
- o Freestyle® Libre 2 Sensor



Heart Failure Agents

Medical necessity criteria updated

- Entresto® (sacubitril/valsartan)
 - The requirement of a reduced ejection fraction of 40% or less has been removed

Miscellaneous Oncology Drugs, 5.01.540

New drugs added to policy

- Lumakras[™] (sotorasib)
 - Treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC)
- o Rylaze[™] (asparaginase erwinia chrysanthemi [recombinant]-rywn)
 - As part of a multi-agent chemotherapy regimen for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL)
- Truseltiq® (infigratinib)
 - Treatment of inoperable locally advanced or metastatic cholangiocarcinoma

Myalept® (metreleptin), 5.01.553

Medical necessity criteria updated

- o Added criterion that this drug is used in addition to diet
- Added requirement that this drug is prescribed by or in consultation with an endocrinologist
- Added daily dose limit
- Revised requirements of metabolic abnormalities
- o Removed requirement that an endocrinologist diagnose leptin deficiency
- Reauthorization criteria now requires documentation that the patient is tolerating therapy, and that there is a decrease in HbA1c and/or fasting triglyceride levels from baseline

Pharmacotherapy of Inflammatory Bowel Disorder, 5.01.563

New drug added to policy

- Zeposia® (ozanimod)
 - Treatment of adult patients with ulcerative colitis

Archived policies

An archived policy is one that's no longer active and is not used for reviews.

Effective August 1, 2021

Lipid Apheresis, 8.02.04



Opioid Antagonists Under Heavy Sedation or General Anesthesia as a Technique of Opioid Detoxification, 3.01.520

Deleted policies

No updates this month

Coding updates

Added codes Effective September 3, 2021

The following codes will require review for medical necessity and prior authorization for services on or after September 3, 2021

American Society of Addiction Medicine (ASAM)

0362T, 0905, 0912, 97151, 97153, 97154, 97155, 97156, 97158, H0015, H0017, H0035, S9480

Arthrotomy Hip, InterQual® Criteria

27269

Spinal Orthosis, 1.03.502

L0622, L0623, L0624

Specialty Rx Non-Oncology Alpha 1- Proteinase Inhibitor, InterQual® Criteria J0256

Surgical Dressings and Wound Care Supplies, 9.01.511

A6205

Wound Debridement, InterQual® Criteria

11008



Effective August 6, 2021

Pharmacotherapy of Cushing's Disease and Acromegaly, 5.01.548

Now requires review for medical necessity and prior authorization.

J2353, J2354, J1930

Effective August 1, 2021

Advanced Therapies for Pharmacological Treatment of Pulmonary Arterial Hypertension, 5.01.522

No longer requires review for medical necessity.

S9347

Diagnosis and Treatment of Sacroiliac Joint Pain, 6.01.23

Now requires review for investigative.

64451

Digital Breast Tomosynthesis, 6.01.526

Now requires review for medical necessity.

77065, 77066, 77067

Magnetic Resonance-Guided Focused Ultrasound, 7.01.109

Now requires review for investigative.

0071T, 0072T

Prescription Digital Therapeutics, 13.01.500

Now requires review for medical necessity.

T1505

Rabies Vaccine, Home, 9.01.508

Now requires review for medical necessity and prior authorization.

90377



Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome, 7.01.101 Now requires review for medical necessity.

21685, 42950

Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome, 7.01.101 Now requires review for investigative.

41512, 41530, S2080

Revised codes Effective August 6, 2021

Site of Service: Infusion Drugs and Biologic Agents, 11.01.523

Currently requires review for medical necessity and prior authorization. Now requires review for Site of Service.

J1429

Removed codes Effective August 1, 2021

Advanced Therapies for Pharmacological Treatment of Pulmonary Arterial Hypertension, 5.01.522

No longer requires review for medical necessity.

S9347

Lipid Apheresis, 8.02.04

No longer requires review for medical necessity and prior authorization. Policy archived.

36516

Lipid Apheresis, 8.02.04

No longer requires review for investigative and prior authorization. Policy archived.

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